SEP - 9 2005

K051876

10. APPENDIXES

10.1. Appendix A (510(k) Summary)

510(k) Summary

In accordance with the Safe Medical Devices Act of 1990, 21CFR 807.92, the following is a summary of the safety and effectiveness information on which the substantial equivalence determination is based. The safety and effectiveness of the *MultiWave XR* laser system derives from a determination of substantial equivalence to the predicated devices listed below.

Applicant	Pacific Quantum Instruments, Inc.
Address	408 Bryant Circle, Suite F-1, Ojai, CA 93023
Contact Person	Gennady L. Nikolaenko, Ph.D., President & CEO
Telephone	(805)-640-8080
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E-mail	nikolaenko@mailnew.com
Device Trade Name	***MultiWave XR***
Common Name	Medical Laser System
Classification Name	Laser surgical instrument for use in general and plastic surgery and dermatology (21 CFR 878.4810), Class II Product Code: GEX – Laser, instrument, surgical, powered Panel: 79
Predicate Devices	1). GentleYAG (*Candela*), K022951, K023193 2). GentleLASE GL (*Candela*), K994260 3). Gemini (*Laserscope*), K034011 4). Aura *i* (*Laserscope*), K024206 5). Apogee Elite (*Cynosure*), K034030 6). Adept 1064/532/755 Laser (*Adept Medical Concepts*) K032218
Device Description	The *MultiWave XR* combines three laser outputs in a single device. It produces a long pulse laser light of 532 *nm*, 755 *nm*, and 1064 *nm* wavelengths. The laser head has two optical cavities containing an Alexandrite crystal rod (755 *nm*) and a Nd:YAG crystal rod (1064 *nm*) with optional frequency doubler installed (532 *nm*). Pulsed laser energy accomplished with a red aiming beam of low energy (*5mW*, 635*nm*) is delivered to a target via an optical fiber and a handpiece. Each laser outlet has own fiber and handpiece. Chilled air is delivered to the same target via jets in a handpiece.
Intended Use	The MultiWave XR laser system is indicated for permanent hair removal, for treatment of vascular lesions, pigmented lesions, and wrinkles

10.2. Appendix B (Summary of Substantial Equivalence)

Summary of Substantial Equivalence

Pacific Quantum Instrument, Inc. believes that its ***MultiWave XR*** laser system is substantially equivalent:

a) regarding all three available in *MultiWave XR* laser emissions together (1064 *nm,* 755 *nm and* 532 *nm),* to the legally marketed device: *Adept 1064/532/755 Laser* (Adept Medical Concepts, Inc., K032218);
b) regarding 1064 *nm* laser emission, to the following legally marketed devices: *Adept 1064/532/755 Laser* (K032218), *GentleYAG* (Candela, K022951), *Gemini* (Laserscope, K034011), *Apogee Elite* (Cynosure, K034030);
c) regarding 755 *nm* laser emission, to the following legally marketed devices: *Adept 1064/532/755 Laser* (K032218), *GentleLASE GL* (Candela, K994260), *Apogee Elite* (Cynosure, K034030);
d) regarding 532 nm laser emission, to the following legally marketed devices: *Adept 1064/532/755 Laser* (K032218), *Gemini* (Laserscope, K034011), *Aura i* (Laserscope, K024206).

All these predicate devices previously cleared for medical applications, which include all Indications for Use of *MultiWave XR* proposed by Pacific Quantum Instruments, Inc. in the Indications for Use Statement (see *Appendix 10.3*)

Technologically, the predicate devices have identical characteristics to the *MultiWave XR* laser system, all comprising a flash lamp pumped Nd:YAG laser rod generating light at 1064 *nm* or 532 *nm*, or a flash lamp pumped Alexandrite laser rod generating light at 755 *nm*, which is subsequently delivered to the patient via individual optical fiber delivery system and focusing handpiece.

Moreover, all lasers are microprocessor controlled devices with internal closed water-air laser cooling system, and Class I, 635 *nm,* aiming pilot lasers, which pose no hazard to the user.

The risk and benefits of the *MultiWave XR* laser system are comparable to the predicate devices when used for similar applications. It is therefore believed that there are no NEW questions of Safety and Effectiveness raised by the introduction of this device: *MultiWave XR* laser system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2005

Gennady L. Nikolaenko, Ph.D.
President and CEO
Pacific Quantum Instruments, Inc.
408 Bryant Circle, Suite F-1
Ojai, California 93023

Re: K051876
Trade/Device Name: MultiWave XR
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 6, 2005
Received: July 11, 2005

Dear Dr. Nikolaenko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson for MNM
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10.3. Appendix C (Indications for Use Statement)

Indications for Use Statement

510(k) number: K051876

Device name: **MultiWave XR**

Indications for use:

The *MultiWave XR* Laser System is indicated for the following uses:

1. The **532 *nm*** wavelength is indicated for: the treatment of Acne, benign vascular, including telangiectasia on the leg and face.

2. The **755 *nm*** wavelength is indicated for: stable long-term or permanent hair reduction. It is used for I-IV skin types. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

3. The **1064 *nm*** wavelength is indicated for: stable long-term or permanent hair reduction. It is used for IV-VI skin types. It also indicated for photocoagulation and hemostasis of dermatological vascular lesions, for incision/excision of soft body tissues in dermatology, and for nonablative wrinkle reduction.

Prescription Use ✓ and/or Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K051876